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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/134,333	08/14/98	LONGACRE-ANDRE S	0660-0135-0X

022850 HM22/1024
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EXAMINER	
TURNER,S	
ART UNIT	**PAPER NUMBER**
1647	14

DATE MAILED: 10/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/134,333	Longacre-andre
Examiner	**Group Art Unit**
Sharon L. Turner, Ph.D.	1647

☒ Responsive to communication(s) filed on 7-24-00

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is clos d** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 68-116 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 68-116 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Response to Amendment

1. The Art Unit of U.S. Patent application SN 09/134,33 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1647.

2. The amendment filed 7-24-00 has been entered into the record and has been fully considered.

3. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

4. Claims 1-67 are canceled. Claims 68-116 are now pending.

Rejections Necessitated by Amendment

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 68-116 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 and 43 of copending Application No. 09/125,031 and claims 1-14 and 37-38 of copending Application No. 09/125,032. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims overlap, in particular the recombinant proteins of the surface protein 1 of the merozoite form of a Plasmodium type parasite, oligomers, protein fragments and vaccination compositions share structural and functional characteristics as recited in the claims of the '031, '032 and instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 68-116 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. This rejection is newly applied as necessitated by amendment perfecting applicants priority. The rejection was not previously made as the prior art references previously cited anticipate applicants invention

and thus provided the skilled artisan with written description support and enablement for the claimed invention. In the absence of the prior art references the skilled artisan at the time of the invention cannot recognize by written description support the encompassed recombinant sequences claimed.

The specification discloses and the claims recite a recombinant protein and vaccinating compositions whose essential constituent polypeptide sequence comprises a 19 kd C-terminal fragment of the surface protein 1 of the merozoite form of a Plasmodium parasite other than Plasmodium vivax, or portions or fragments thereof. These descriptions fail to meet the written description provisions of 35 USC 112, first paragraph because the recombinant protein polypeptide residues are not defined and thus fail to meet the written description provision of 35 USC 112, first paragraph.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is for purposes of the 'written description' inquiry, whatever is now claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed amino acids and recombinant protein generated thereby. Conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific residues are required.

See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, the claims fail to meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

9. Claims 68-116 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is newly applied as necessitated by amendment perfecting applicants priority. The rejection was not previously made as the prior art references previously cited anticipate applicants invention and thus provided the skilled artisan with written description support and enablement for the claimed invention. In the absence of the prior art references the skilled artisan at the time of the invention cannot recognize by written description support the encompassed recombinant sequences claimed and further cannot make and use the recombinant proteins absent further undue experimentation as set forth below.

The specifications disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

Claims 68-116 are drawn to a recombinant protein and vaccinating compositions comprising the recombinant protein yet the claims fail to identify the amino acids of the recombinant protein to be generated by recombinant methods. The claims recite characteristics of the recombinant protein including a 19 kd (p19) C-terminal fragment of the surface protein 1 of the merozoite form (MSP-1 protein) of a Plasmodium parasite that is infectious in man, other than Plasmodium vivax, wherein said C-terminal fragment remains anchored to the surface of said Plasmodium parasite at the end of its penetration phase into human erythrocytes during an infectious cycle; or a portion of said 19 kilodalton (p19) C-terminal fragment other than a fragment from Plasmodium vivax, which induces an immune response which can inhibit parasitemia *in vivo* in a host infected with said Plasmodium parasite; wherein said recombinant protein comprises conformational epitopes recognized by human antisera and is unstable in a reducing agent.

The specification teaches MSP-1p42 comprises MSP-1p19 and further that immune sera from monkeys from either peptide cross react. Both peptides possess reduction sensitive immune epitopes, see in particular p. 48 of the specification. However, the specification fails to teach

those amino acid portions which are required for activity such as conformational epitopes recognized by human antisera which are unstable in a reducing agent. The epitopes are ill-defined as the amino acids required are not disclosed. Further, the specification fails to teach those specific epitopes which are comprised in the falciparum peptides which are not in common to the vivax parasite species. Therefore, the skilled artisan would require further undue experimentation to determine the epitopes of the recited protein which are recited in the claim and further to test the vivax species such as to exclude those epitopes shared in common.

The art teaches that the prediction of immunoreactive epitopes of a full length protein and immunoreactive epitopes of species variants which differ in primary amino acid structure are unpredictable in the art, see in particular Choh et al., PNAS 77(6):3211-14, 1980. Thus, the specification lacks the guidance required by the skilled artisan to develop and test with reasonable probability the recombinant protein epitopes and fragments of the claims. The specification fails to teach an epitope fragment which comprises the ability to inhibit parasitemia *in vivo* in a host infected with said Plasmodium parasite. The specification merely show that the p19 fragment may inhibit parasitemia, see in particular p. 26-27 of the specification. Thus, the skilled artisan would require further undue experimentation to define those epitopes sufficient to inhibit parasitemia *in vivo* in a host infected with said Plasmodium parasite.

In addition, the skilled artisan recognizes the unpredictability in the art associated with the prediction of peptide function based upon divergent structure, see in particular Skolnick et al., Trends in Biotech 18(1):34-39, 2000, abstract and Box 2. Thus, for those divergent peptide

epitope structures, the skilled artisan would be required to perform further undue experimentation to discover those peptides which possess the immunoreactive and inhibiting properties of Plasmodium infection other than P. vivax. Thus, for these reasons, it would take further undue experimentation on behalf of the skilled artisan to make and to use the claimed invention.

Priority

10. Acknowledgment is made of applicant's claim for priority based on FR96/01822, an application filed internationally on 2-14-96. Applicant has now provided the proper english translation of the FR96/01822 and PCTFR97/00290. It is noted, however, that in agreement with applicant's admission, that claims 70, 78, 95 and 104 do not appreciate the benefit of applicant's priority date of 2-14-96. Thus, the priority date granted claims 70, 78, 95 and 104 is the instant filing date 8-14-98. New art rejections are applied as necessitated by applicants amendment perfecting priority.

Claim Rejections - 35 USC § 102 or 103

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

12. Claims 70 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Shi et al, Infection and Immunity, July 1996, 64(7):2716-2723 as evidenced by Eagan et al, Infection and Immunity, August 1997, 65(8):3024-3031.

Shi et al teach the recombinant protein of claims 68 and 89, see in particular the title, p. 2716, Natural Immune Response to the C-terminal 19 kDa Domain of Plasmodium falciparum Merozoite Surface Protein 1. The protein is recombinant, being produced in yeast, see in particular abstract, line 3. The Plasmodium type parasite is Plasmodium falciparum which is other than P. vivax. The recombinant protein inherently comprises conformational epitopes which are unstable in a reducing medium because as the protein contains disulfide bonds which are hydrolyzed in reducing medium. The protein constitutes epitopes recognized by human antisera formed against plasmodium, see in particular abstract, lines 6-10, p. 2716. Thus the reference teachings anticipate the recombinant protein of claims 68 and 89. The Shi protein elicits a long term memory response, see in particular abstract, p. 2716. The MSP-1p42 is a larger peptide precursor which shares in common epitopes of p19, see in particular Eagan et al, Figure 1, p. 3025. The p19 C-terminal fragment does not include the C-terminal region of p33 and the EGF domains are within the 19 kDa fragment, see in particular Shi et al, p. 2716, col. 2, lines 1-14. As the recombinant peptides of Shi et al. are identical to the characteristics of instant claims, the Shi et al., peptide inherently possess the atomic coordinates in Annexes I, II or III and

the NMR fingerprints of Figures 12.0A to 12.2C as claimed, absent convincing factual evidence to the contrary.

13. Claims 70 and 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Eagan et al, Infection and Immunity, August 1997, 65(8):3024-3031.

Eagan et al teach the recombinant peptides of claims 68, and 89, see in particular figure 1, synthetic peptides P1-P9 corresponding to portions of the entire MSP-1 p19 sequence and recombinant antigens produced as fusion proteins with the glutathione S-transferase protein using pGEX vectors transformed in E. coli, see in particular Antigens, p. 3025, col. 1, line 33-col. 2, line 14 which comprise the p19 C-terminal fragment as claimed. In particular, Well-19 and MAD20 comprise the entire p19 protein, P1-P9 comprise a portion of that fragment. The peptides P1-P9 share one amino acid of p19 (a portion of that fragment) and a single amino acid of the p33 fragment which contains less than 10 amino acid residues. The proteins contain conformational epitopes which are unstable in reducing medium and which constitute the majority of the epitopes recognized by human antisera formed against Plasmodium. As the recombinant peptides of Eagan et al. are identical to the characteristics of instant claims, the Eagan et al., peptide inherently possess the atomic coordinates in Annexes I, II or III and the NMR fingerprints of Figures 12.0A to 12.2C as claimed, absent convincing factual evidence to the contrary.

14. Claims 70 and 95 are rejected under 35 U.S.C. 102 (b) as being anticipated by Holm et al, Mol. & Biochem. Parasitol., 89:313-319, 1997.

Holm et al teach the recombinant protein of claims 68 and 89 comprising a portion or a peptide capable of inducing an immune response. The recombinant protein comprises epitopes which are recognized or not recognized when in the nonreduced and reduced forms respectively, see Figure 1, thus inherently comprising the coordinates of the recombinant proteins. MSP-1p19 comprises the two EGF domains. P. cynomolgi protein shares a portion or fragment of the peptide which is capable of inducing an immune response, see in particular Figures 1-2 recognition by immune antisera. Thus, the reference teachings anticipate the claimed recombinant proteins. As the recombinant peptides of Holm et al. are identical to the characteristics of instant claims, the Holm et al., peptide inherently possess the atomic coordinates in Annexes I, II or III and the NMR fingerprints of Figures 12.0A to 12.2C as claimed, absent convincing factual evidence to the contrary.

15. Claims 68-116 are rejected under 35 U.S.C. 102(a) as being by Chang et al., Infection & Immun., Jan., 1996, 64(1):253-261.

Chang et al., teach a rMSP-1 $_{19}$ construct corresponding to the FUP MSP-1 coding region from Asn-1613 to Ser-1705 and is expressed as a fusion protein with the preprosequence of yeast alpha factor and a C-terminal six histidine tag, see in particular p. 254, Antigen Preparation, column 1, lines 13-16. This construct comprises a 19 kd C-terminal fragment of the surface protein 1 of the merozoite form of a plasmodium falciparum species and induces long term memeory immune responses which inhibit parasitemia see in particular p. 255, column 1, lines 39, Table 1 and p. 258, column 1, lines 22-35. The MSP-1p42 fragment comprises MSP-1p19

residues, see in particular discussion as set forth above and in Paper No. 11 mailed 1-26-00. The recombinant MSP-1 p19 peptides inherently contain epitopes which are unstable in reducing media because the peptides comprise disulfide bonds which are reduced in reducing medium. The peptides inherently comprise the characteristics of the recombinant peptide including the claimed atomic coordinates and NMR finger prints. Thus, the reference teachings anticipate the claimed invention.

16. Claims 68-116 are rejected under 35 U.S.C. 102(e) as being by anticipated by Druilhe et al., US Patent No. 5,690,941, filed May 13, 1994.

Druilhe et al., teach recombinant peptides and fragments thereof which are recognized by antibodies to the sporozoite of Plasmodium falciparum. The peptides inherently comprise a portion of the p19 C-terminal fragment of the merozoite form other than P. vivax which induces a long term memory immune response which can inhibit against parasitemia, which comprises conformational epitopes unstable in reducing medium, does not contain or contains less than 50 or 10 residues of a polypeptide sequence of amino acids in the C-terminal region of p33 and contains the two EGF regions of the p19 protein, absent convincing factual evidence to the contrary. The recombinant peptides inherently contain epitopes which are unstable in reducing media and which comprises the characteristics of the recombinant peptide including the claimed atomic coordinates and NMR finger prints. Thus, the reference teachings anticipate the claimed invention.

17. Claims 68-116 are rejected under 35 U.S.C. 102(e) as being anticipated by Holder et al., US Patent 5,720,859, filed Feb. 22, 1993.

Holder et al., teach 19kda C-terminal fragments of the merozoite surface protein (MSP-1) which comprises 2 EGF regions of the p19 protein. The peptides are inherently characterized by the ability to induce long term memory immune responses and to inhibit parasitemia *in vivo.* Thus, the reference teachings anticipated the claimed invention.

18. Claims 68-116 are rejected under 35 U.S.C. 102(b) as being anticipated by Eagan et al., Infection & Immunity, Feb. 1995, p. 456-466.

Eagan et al., teach serum antibodies to conserved epitopes formed by the two EGF motifs of MSP-1p19 C-terminal fragment of the major merozoite surface protein of Plasmodium falciparum, see in particular title, abstract and p. 457, Recombinant PfMSP1 proteins, column 1, lines 1-22, p. 458, column 2, lines 3-13 which teach reduced and non reduced antigens including recombinant proteins which induce an immune response and which inherently inhibit parasitemia *in vivo.* The recombinant peptides inherently comprise the characteristics of the claimed recombinant peptide including the claimed atomic coordinates and NMR finger prints. Thus, the reference teachings anticipate the claimed invention.

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 68-116 are provisionally rejected under 35 U.S.C. 103(a) as being unpatentable over claims 1-19 and 43 of copending Application No. 09/125,031 and claims 1-14 and 37-38 of copending Application No. 09/125,032.

Claims 68-116 are drawn to recombinant proteins and vaccinating compositions. These products as claimed in claims 68-116 correspond to a recombinant protein...fragment of the surface protein 1 of the merozoite form (MSP-1 protein) of a Plasmodium type parasite...against the corresponding Plasmodium. As such, these elements are shared, see in particular the '031 and '032 applications which are also drawn to recombinant proteins and vaccination compositions as claimed in claims 1-19 and 43 of copending Application No. 09/125,031 and claims 1-14 and 37-38 of copending Application No. 09/125,032 which correspond to a recombinant protein...fragment of the surface protein 1 of the merozoite form (MSP-1 protein) of

a Plasmodium type parasite...against the corresponding Plasmodium. Thus, the '031 and '032 applications teachings render obvious the instantly claimed invention.

21. Claims 68-116 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over claims 1-19 and 43 of copending Application No. 09/125,031 and claims 1-14 and 37-38 of copending Application No. 09/125,032, which has common inventors, but different assignees with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application. The instantly claimed invention is obvious over the '031 and '032 applications as set forth above, provisional rejection under 35 U.S.C. 103(a).

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131.

Status of Claims

22. No claims are allowed.

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

24. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.
October 23, 2000

CHRISTINE SAOUD
PATENT EXAMINER
Christine Saoud